AUG 7 2000

K001471

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Hedrocel Acetabular Augment

Submitter Name And Address:	Implex Corp. 80 Commerce Drive Allendale, New Jersey 07401-1600
Contact Person:	John Schalago
Phone Number:	(201) 818-1800
Fax Number:	(201) 995-9722
Date Prepared:	May 10, 2000
Device Trade Name:	Hedrocel Acetabular Augment
Device Common Name:	Acetabular augmentation devices for total hip replacement acetabular components
Classification Number and Name:	21 CFR § 888.3358

Substantial Equivalence:

The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without premarket approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

Device Description:

The Hedrocel Acetabular Augment provides an alternative to structural allograft for augmenting moderate to large-sized segmental acetabular defects encountered in acetabular reconstruction. The Hedrocel Acetabular Augment possesses a truncated hemispherical geometry with an inner diameter 3mm larger than the major diameter of the corresponding acetabular cup. The device is available in OD sizes 40 to 70 mm in 2 mm increments, and each size is offered in thicknesses from 5mm to 30mm in 5 mm increments. The Hedrocel Acetabular Augment incorporates portals that allow for the use of commercially available Continuum Bone Screws, 5mm and 6.5mm, for adjunct fixation of the acetabular component and surrounding bone.

Indications for Use:

The Implex Hedrocel Acetabular Augment is intended to provide the orthopedic surgeon with a prosthetic alternative to structural allograft in cases of segmental acetabular deficiencies.

The Hedrocel Acetabular Augment is affixed to the mating porous acetabular cup using PMMA bone cement. The assembled Hedrocel Acetabular Augment /Acetabular Cup construct is intended for cemented or cementless use.

Device Technological Characteristics and Comparison to Predicate Device:

A comparison of device technological characteristics and properties demonstrates that the device is substantial equivalent to the cited predicate devices.

Performance Data:

The Hedrocel/bone Cement interface was tested per applicable standards (or draft standards) and the results demonstrated that the interface will maintain its integrity under physiological loads.

Conclusion:

The Implex Hedrocel Acetabular Augment is substantially equivalent to the following predicate devices: Hedrocel Femoral and Tibial Spacers, Hedrocel Acetabular Cups (Primary and Revision), Hedrocel Acetabular Restrictor, Osteonics Acetabular Wedge System, and Biomet M.A.R.S..

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 7 2000

Mr. John A. Schalago
Manager, Regulatory Affairs
Implex Corporation
80 commerce Drive
Allendale, New Jersey 07401-1600

Re: K001471
Trade Name: Implex Hedrocel Acetabular Augment
Regulatory Class: II
Product Code: LWJ, LPH
Dated: May 10, 2000
Received: May 11, 2000

Dear Mr. Schalago:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Bachner

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K001471

Device Name: The Implex Hedrocel Acetabular Augment

Indications For Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of Device Evaluation (ODE)

Diane R. Vochmer.

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001471

Prescription Use (Per 21 CFR 801.109) Yes OR... Over-The-Counter Use No

(Optional Format 1-2-96)